

K020022

FEB 01 2002

**SUMMARY OF SAFETY AND EFFECTIVENESS**

Dec 31 ,2001

**DINAMAP® Pro Series 110-410 Monitor****A. Submitter**

GE Medical Systems Information Technologies  
4502 Woodland Corporate Boulevard  
Tampa, FL 33614

**B. Company Contact**

Thomas J English  
Director, Regulatory Affairs  
Phone: 813-887-2107  
Fax: 813-887-2413

**C. Common Name**

Physiological or Vital Signs Monitor, Patient Monitor

Classification Name	Product Code	21 CFR
System, Measurement, Blood Pressure, Noninvasive	DXN	870.1130
Computer, Blood Pressure	DSK	870.1110
Alarm, Blood Pressure	DSJ	870.1100
Oximeter	DQA	870.2700
Oximeter, Ear	DPZ	870.2710
Thermometer, Clinical Electronic	FLL	880.2910
Recorder, Paper Chart	DSF	870.2810

**D. Predicate/Legally Marketed Devices**

DINAMAP® Pro Series Monitor 100-400-K992638  
Critikon Company, LLC

**E. Device Description**

The DINAMAP Pro Series 110-410 Monitor is a prescription device intended for use only by health care professionals. Four configurations of the monitor-all with integrated printer-will offer the following vital signs parameters:

- DINAMAP 110: Non-Invasive Blood Pressure and Pulse Rate
- DINAMAP 210: Non-Invasive Blood Pressure and Pulse Rate, Temperature
- DINAMAP 310M: Non-invasive Blood Pressure and Pulse Rate, Pulse Oximetry
- DINAMAP 410M: Non-Invasive Blood Pressure and Pulse Rate, Pulse Oximetry and Temperature.

This portable device includes an integrated printer and is capable of operation from an external AC mains power source or an internal lead-acid rechargeable battery.

**F. Intended Use**

The DINAMAP® Pro Series 110-410 Monitor is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport. Vital signs parameters include non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, and/or oxygen saturation (pulse oximetry) and/or temperature. The portable device is designed for use in numerous clinical settings in various hospital departments such as emergency, radiology, recovery, medical/ surgical, labor and delivery, endoscopy, cardiac step-down. It can also be used in satellite areas, physicians' offices, or alternate care settings.

**G. Technological Characteristics**

The DINAMAP® Pro Series 110-410 Monitor has the same technological characteristics as the predicate device, the DINAMAP® Pro Series 100-400 Monitor. There are no new technologies used on the DINAMAP® Pro Series 110-410 Monitor.

**H. Parameter Technology**

The DINAMAP® Pro Series 110-410 Monitor has the following parameter technologies:

- NIBP ASAP algorithm wholly implemented from the DINAMAP Pro 1000 Monitor
- Wholly implemented Alaris IVAC Turbo thermometry technology
- Wholly implemented Masimo SpO2 SET technology

**I. Testing**

Several bench studies were conducted which demonstrate safety and effectiveness of the DINAMAP® Pro Series 110-410 Monitor:

- Mechanical and Environmental
- Electromagnetic Compatibility
- Electrical Safety

**K. Substantial Equivalence**

Pro Series 110-410	Predicate Device & Model	510(k) Numbers
Monitor	DINAMAP Pro Series 100-400	K992638
Pulse Oximetry	Masimo	K992238
Temperature	Alaris Medical System	K955846
NIBP	DINAMAP Pro 1000	K002248



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 01 2002

Mr. Thomas English  
Director, Regulatory Affairs  
GE Medical Systems Information Technologies  
4502 Woodland Corporate Blvd.  
Tampa, FL 33614

Re: K020022  
Trade Name: DINAMAP® Pro Series 110-410 Monitor  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac Monitor (Including Cardiometer and Rate Alarm)  
Regulatory Class: Class II (two)  
Product Code: MWI  
Dated: December 31, 2001  
Received: January 3, 2002

Dear Mr. English:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 - Mr. Thomas English

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.  
Acting Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K020022

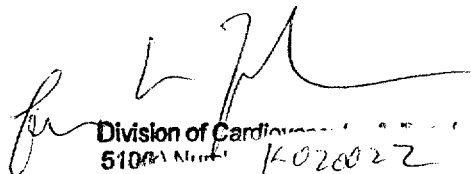
Device Name: DINAMAP® Pro Series 110-410 Monitor

### Indications for Use:

The DINAMAP® Pro Series 110-410 Monitor is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport. Vital signs parameters include non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate and/or temperature and/or oxygen saturation (pulse oximetry). The portable device is designed for use in numerous clinical settings in various hospital departments such as emergency, radiology, recovery, medical/surgical, labor and delivery, endoscopy, cardiac step-down. It can also be used in satellite areas, physicians' offices, or alternate care settings.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular Devices  
510(k) Number: K020022

Prescription Use ✓  
(per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)